

06-01-09

Docket 17675 (BOT)

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**



Applicant: ERIC R. FIRST ) Examiner:  
Serial Number: 10/817,036 )  
Filed: April 2, 2004 ) Art Unit:  
For: THERAPY FOR MELANIN ) Confirmation No.  
          RELATED AFFLICTIONS )  
                                  ) Irvine, California

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Arlington, VA 22313-1450

Dear Sir:

Applicant's provide with regard to the patent application entitled THERAPY FOR MELANIN RELATED AFFLICTIONS, filed herewith one copy of a documents of which they are aware, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. A listing of documents submitted is set forth on the attached Information Disclosure Citation (Form PTO-1449).

While these documents may be material pursuant to 37 C.F.R. §1.56, their disclosure is not intended to constitute an admission that the documents are prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge any fees required or necessary for the filing, processing or entering of this paper or any of the enclosed papers, and to refund any overpayment, to deposit account 01-0885.

Respectfully submitted,

Date: May 27, 2004



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Registration Number 33,433

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#### **CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10**

I hereby certify that this Information Disclosure Statement and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date **May 27, 2004**, in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EL385492540US addressed to Mail Stop: Patent Application, Commissioner for Patents, P.O. Box 1450, Arlington, VA 22313-1450.

Susan Bartholomew  
Name of person mailing paper



Signature of person mailing paper

Date: May 27, 2004



**LIST OF ART CITED BY APPLICANT**

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**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
AA	10/194805	-	Donovan, Stephen			7/11/2002
AB	10/731973	-	First, Eric F.			12/7/2003
AC	2003 0224019	12/4/2003	O'Brien, Christopher			
AD	5,437,291	8/1/1995	Pasricha et al.			
AE	5,670,484	9/23/1997	Binder, William J.			
AF	5,714,468	2/3/1998	Binder, William J.			
AG	5,766,605	6/16/1998	Sanders et al.			
AH	5,989,545	11/23/1999	Foster et al.			
AI	6,063,768	5/16/2000	First, Eric R.			
AJ	6,139,845	10/31/2000	Donovan, Stephen			
AK	6,299,893	10/9/2001	Schwartz et al.			
AL	6,306,423	10/23/2001	Donovan et al.			
AM	6,312,708	11/6/2001	Donovan, Stephen			
AN	6,423,319	7/23/2002	Brooks et al.			
AO	6,447,787	9/10/2002	Gassner et al.			
AP	6,458,365	10/1/2002	Aoki et al.			
AQ	6,464,986	10/15/2002	Aoki et al.			

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
BA	GB 2,368,281	8/31/2001	UK			Y
BK	WO 02/09743	2/7/2002	PCT			Y
	WO 03/011333	2/13/2003	PCT			Y

**OTHER ART**  
(Including Author, Title, Date, Pertinent Pages, etc.)

CA	Andreadis S., et al., <i>Keratinocyte growth factor induces hyperproliferation and delays differentiation in a skin equivalent model system</i> , FASEB J. 2001 Apr;15(6):898-906
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	CB	Aoki K., et al, <i>Mechanisms of the antinociceptive effect of subcutaneous Botox: Inhibition of peripheral and central nociceptive processing</i> , Cephalgia 2003 Sep;23(7):649
	CC	Arredondo J., et al., <i>Central role of alpha7 nicotinic receptor in differentiation of the stratified squamous epithelium</i> , J Cell Biol. 2002 Oct 28;159(2):325-36
	CD	Asahina A., et al., <i>Specific induction of cAMP in Langerhans cells by calcitonin gene-related peptide: relevance to functional effects</i> , Proc Natl Acad Sci U S A. 1995 Aug 29;92(18):8323-7
	CE	Bigalke H., et al., <i>Botulinum A Neurotoxin Inhibits Non-Cholinergic Synaptic Transmission in Mouse Spinal Cord Neurons in Culture</i> , Brain Research 360;318-324:1985
	CF	Bigalke H., et al., <i>Tetanus Toxin and Botulinum A Toxin Inhibit Release and Uptake of Various Transmitters, as Studied with Particulate Preparations From Rat Brain and Spinal Cord</i> , Naunyn-Schmiedeberg's Arch Pharmacol 316;244-251:1981
	CG	Binz T. et al., <i>The Complete Sequence of Botulinum Neurotoxin Type A and Comparison with Other Clostridial Neurotoxins</i> , J Biological Chemistry 265(16):9153-9158:1990
	CH	Blugerman G., et al., <i>Multiple eccrine hidrocystomas: A new therapeutic option with botulinum toxin</i> , Dermatol Surg 2003 May;29(5):557-9
	CI	Brem, H., et al, <i>Placebo-Controlled Trial of Safety and Efficacy of Intraoperative Controlled Delivery by Biodegradable Polymers of Chemotherapy for Recurrent Gliomas</i> , Lancet 345;1008-1012:1995
	CJ	Bushara K., <i>Botulinum toxin and rhinorrhea</i> , Otolaryngol Head Neck Surg 1996;114(3):507
	CK	Chen W., et al., <i>Trophic interactions between sensory nerves and their targets</i> , Journal of Biomedical Science. 1999;6(2):79-85
	CL	Chiang H-Y, et al., <i>Regional difference in epidermal thinning after skin denervation</i> , Exp Neurol 1998;154(1):137-45
	CM	Dabrowski et al, <i>Botulinum toxin as a novel treatment for self mutilation in Lesch-Nyhan syndrome</i> , Ann Neurol 2002 Sep;52(3 Supp 1):S157
	CN	Duggan et al.; <i>A survey of Botulinum neurotoxin substrate expression in cells</i> ; Mov Disord, 10(3):376:1995
	CO	Friedland S, et al., <i>Porcelinizing discolorization of the periocular skin following botulinum a toxin injections</i> . J. Neuro-Ophthalmol 1996 Mar;16(1):70-2

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	CP	Fung L. K. et al., <i>Pharmacokinetics of Interstitial Delivery of Carmustine 4-Hydroperoxycyclophosphamide and Paclitaxel From a Biodegradable Polymer Implant in the Monkey Brain</i> , Cancer Research 58;672-684:1998
	CQ	Gonelle-Gispert et al.; <i>Snap-25a and -25b isoforms are both expressed in insulin-secreting cells and can function in insulin secretion</i> ; Biochem J 1;339 (pt 1):159-65:1999
	CR	Grando S., <i>Biological functions of keratinocyte cholinergic receptors</i> , J Investig Dermatol Symp Proc. 1997 Aug;2(1):41-8
	CS	Grando S., et al., <i>Activation of keratinocyte nicotinic cholinergic receptors stimulates calcium influx and enhances cell differentiation</i> . Invest Dermatol. 1996 Sep;107(3):412-8
	CT	Grando S., et al., <i>Human keratinocytes synthesize, secrete, and degrade acetylcholine</i> J Invest Dermatol. 1993 Jul;101(1):32-6
	CU	Grando S., et al., <i>Keratinocyte muscarinic acetylcholine receptors: immunolocalization and partial characterization</i> , J Invest Dermatol. 1995 Jan;104(1):95-100
	CV	Griffin J., et al., <i>Axonal degeneration and disorders of the axonal cytoskeleton</i> . In: Waxman S., et al., The Axon. New York: Oxford University Press, 1995:375-390
	CW	Habermann E., et al., <i>Tetanus Toxin and Botulinum A and C Neurotoxins Inhibit Noradrenaline Release From Cultured Mouse Brain</i> , J Neurochem 51(2):522-527:1988)
	CX	Habermann E., <i>Inhibition by Tetanus and Botulinum A Toxin of the release of [3H]Noradrenaline and [3H]GABA From Rat Brain Homogenate</i> , Experientia 44;224-226:1988
	CY	Habermann, <i>I-Labeled Neurotoxin from Clostridium Botulinum A: Preparation, Binding to Synaptosomes and scent to the Spinal Cord</i> ; Nauny-Schmiedeberg's Arch. Pharmacol. 1974; 281, 47-56
	CZ	<i>Harrison's Principles of Internal Medicine</i> (1998), edited by Anthony Fauci et al., 14th edition, published by McGraw Hill
	CAA	Heckmann M., et al., <i>Botulinum toxin type A injection in the treatment of lichen simplex: An open pilot study</i> , J Am Acad Dermatol 2002 Apr;46(4):617-9
	CBB	Hokfelt T., <i>Neuropeptides in perspective : The last ten years</i> , Neuron 1991; 7: 867-879

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CCC	Hosoi J., et al., <i>Regulation of Langerhans cell function by nerves containing calcitonin gene-related peptide</i> , Nature. 1993 May 13;363(6425):159-63
CDD	Hsieh S., et al., <i>Epidermal denervation and its effects on keratinocytes and Langerhans cells</i> , J Neurocytol 1996;25:513-524
CEE	Hsieh S., et al., <i>Modulation of keratinocyte proliferation by skin innervation</i> . Journal of Investigative Dermatology, 1999;113(4):579-86
CFF	Hsieh S., et al., <i>Pathology of nerve terminal degeneration in the skin</i> , Journal of Neuropathology & Experimental Neurology. 2000;59(4):297-307
CGG	Hsieh S., et al., <i>Skin Innervation and Its Effects on the Epidermis</i> , J Biomed Sci. 1997;4(5):264-268
CHH	Hsiung-F., et al., (2001) <i>Quantitative pathology of cutaneous nerve terminal degeneration in the human skin</i> , Acta Neuropathologica 102:455-461
CII	Huang, et al., <i>Influence of cutaneous nerves on keratinocyte proliferation and epidermal thickness in mice</i> , Neuroscience 94 :965-973, 1999
CJJ	Inaba N., et al., <i>Capsaicin-induced calcitonin gene-related peptide release from isolated rat stomach measured with a new chemiluminescent enzyme immunoassay</i> , Jpn J Pharmacol. 1996 Nov;72(3):223-9
CKK	Ishikawa H et al., <i>Presynaptic effects of botulinum toxin type A on the neuronally evoked response of albino and pigmented rabbit iris sphincter and dilator muscles</i> , Jpn J Ophthalmol 2000 Mar 4;44(2):106-109
CLL	Jacks, L., et al., <i>Idiopathic toe walking: Treatment with botulinum toxin A injection</i> , Dev Med Child Neurol 2002;44(Suppl 91):6
CMM	Jankovic J. et al., <i>Therapy With Botulinum Toxin</i> , Marcel Dekker, Inc., (1994), page 5, 150
CNN	Johnson M., <i>Synaptic glutamate release by postnatal rat serotonergic neurons in microculture</i> , Neuron 1994; 12: 433-442
COO	Jost, Wolfgang; <i>Ten years' experience with Botulin toxin in anal fissure</i> ; Int J Colorectal Dis 2002 Sep;17(5):298-302
CPP	Kaneko T., et al., <i>Immunohistochemical demonstration of glutaminase in catecholaminergic and serotonergic neurons of rat brain</i> , Brain Res. 1990; 507: 151-154
CQQ	Kasakov L., et al., <i>Direct evidence for concomitant release of noradrenaline, adenosine 5'-triphosphate and neuropeptide Y from sympathetic nerve supplying the guinea-pig vas deferens</i> . J. Auton. Nerv. Syst. 1988; 22: 75-82

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CRR	Katsambas A., et al., <i>Cutaneous diseases of the foot: Unapproved treatments</i> , Clin Dermatol 2002 Nov-Dec;20(6):689-699
CSS	Ko M., et al., <i>Cutaneous nerve degeneration induced by acrylamide in mice</i> , Neuroscience Letters. (2000)293(3):195-8
CTT	Komuves et al.; <i>Epidermal Expression of the Full-Length Extracellular Calcium-Sensing Receptor Is Required for Normal Keratinocyte Differentiation</i> ; Journal of Cellular Physiology 2002 Jul;192(1):45-54
CUU	Krnjevic K., <i>Central cholinergic mechanisms and function</i> . Prog Brain Res. 1993;98:285-92
CVV	Kupfermann I., <i>Functional studies of cotransmission</i> . Physiol. Rev. 1991; 71: 683-732.48: 545-59
CWW	Lee M., et al., <i>Clinical and electrophysiological characteristics of inflammatory demyelinating neuropathies</i> , Acta Neurol Taiwan 1997;6:283-288
CXX	Legat F., et al., <i>Repeated subinflammatory ultraviolet B irradiation increases substance P and calcitonin gene-related peptide content and augments mustard oil-induced neurogenic inflammation in the skin of rats</i> , Neurosci Lett. 2002 Sep 6;329(3):309-13
CYY	Li Y., et al., <i>Sensory and motor denervation influences epidermal thickness in rat foot glabrous skin</i> , Exp Neurol 1997;147:452-462(see page 459)
CZZ	Lin Y., et al., <i>Quantitative sensory testing: normative values and its application in diabetic neuropathy</i> , Acta Neurol Taiwan 1998;7:176-184
CAAA	Lin Y., et al., (2001) <i>Cutaneous nerve terminal degeneration in painful mononeuropathy</i> , Experimental Neurology. 170(2):290-6
CBBB	Lundberg J., <i>Pharmacology of cotransmission in the autonomic nervous system: Integrative aspects on amines, neuropeptides, adenosine triphosphate, amino acids and nitric oxide</i> , Pharmacol. Rev. 1996; 48: 113-178
CCCC	McCarthy B., et al., <i>Cutaneous innervation in sensory neuropathies: evaluation by skin biopsy</i> , Neurol 1995;45:1848-1855
CDDD	Moyer E et al., <i>Botulinum Toxin Type B: Experimental and Clinical Experience</i> , being chapter 6, pages 71-85 of "Therapy With Botulinum Toxin", edited by Jankovic, J. et al. (1994), Marcel Dekker, Inc.
CEEE	Naumann et al.; <i>Botulinum toxin type A in the treatment of focal, axillary and palmar hyperhidrosis and other hyperhidrotic conditions</i> ; European J. Neurology 6 (Supp 4): S111-S1150:1999

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	CFFF	Ndoye A., et al., <i>Identification and mapping of keratinocyte muscarinic acetylcholine receptor subtypes in human epidermis</i> , J Invest Dermatol. 1998 Sep;111(3):410-6
	CGGG	Nguyen V., et a., <i>Keratinocyte acetylcholine receptors regulate cell adhesion</i> Life Sci. 2003 Mar 28;72(18-19):2081-5;
	CHHH	Nguyen V., et al., <i>Programmed cell death of keratinocytes culminates in apoptotic secretion of a humectant upon secretagogue action of acetylcholine</i> J Cell Sci. 2001 Mar;114(Pt 6):1189-204
	CIII	Nicholas A. et al., <i>Glutamate-like immunoreactivity in medulla oblongata catecholamine/substance P neurons</i> , NeuroReport 1990; 1: 235-238
	CJJJ	Palacios J., et al., <i>Cholinergic neuropharmacology: an update</i> , Acta Psychiatr Scand Suppl. 1991;366:27-33
	CKKK	Pan C., et al., (2001) <i>Degeneration of nociceptive nerve terminals in human peripheral neuropathy</i> , Neuroreport. 12(4):787-92
	CLLL	Pearce, L.B., <i>Pharmacologic Characterization of Botulinum Toxin For Basic Science and Medicine</i> , Toxicon 35(9);1373-1412 at 1393
	CMMN	Ragona et al.; <i>Management of Parotid Sialocele With Botulinum Toxin</i> ; The Laryngoscope 109:1344-1346:1999
	CNNN	Roehm Pamela C. et al., <i>Prevalence of periocular depigmentation after repeated botulinum toxin a injections in African American patients</i> , J Neuro-Ophthalmol 1999;19(1):7-9
	COOO	Rogers J., et al., <i>Injections of botulinum toxin A in foot dystonia</i> , Neurology 1993 Apr;43(4 Suppl 2
	CPPP	Sanchez-Prieto, J., et al., <i>Botulinum Toxin A Blocks Glutamate Exocytosis From Guinea Pig Cerebral Cortical Synaptosomes</i> , Eur J. Biochem 165;675-681:1897
	CQQQ	Schantz, E.J., et al, <i>Properties and use of Botulinum toxin and Other Microbial Neurotoxins in Medicine</i> , Microbiol Rev. 56;80-99:1992
	CRRR	Sevim, S., et al., <i>Botulinum toxin-A therapy for palmar and plantar hyperhidrosis</i> , Acta Neurol Belg 2002 Dec;102(4):167-70
	CSSS	Singh, <i>Critical Aspects of Bacterial Protein Toxins</i> , pages 63-84 (chapter 4) of Natural Toxins II, edited by B.R. Singh et al., Plenum Press, New York (1976)
	CTTT	Sloop et al.; <i>Reconstituted Botulinum toxin type A does not lose potency in humans if it is refrozen or refrigerated for 2 weeks before use</i> ; Neurology, 48:249-53:1997

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CUUU	Sneddon P., et al., <i>Pharmacological evidence that adenosine triphosphate and noradrenaline are cotransmitters in the guinea-pig vas deferens</i> . J. Physiol. 1984; 347: 561-580
CVVV	Suputtitada, A., <i>Local botulinum toxin type A injections in the treatment of spastic toes</i> , Am J Phys Med Rehabil 2002 Oct;81(10):770-5
CWWV	Weigand et al, <i>I-Labelled Botulinum A Neurotoxin: Pharmacokinetics in Cats after Intramuscular Injection</i> ; Nauny-Schmiedeberg's Arch. Pharmacol. 1976; 292, 161-165
CXXX	Whitehouse P., et al., <i>Nicotinic and muscarinic cholinergic receptors in Alzheimer's disease and related disorders</i> , J Neural Transm Suppl. 1987;24:175-82
CYYY	Wu T., et al., <i>Demonstration of human papillomavirus (HPV) genomic amplification and viral-like particles from CaSki cell line in SCID mice</i> , J Virol Methods 1997;65:287-298
CZZZ	Xu Z-QD et al, <i>Galanin/GMAP- and NPY-like immunoreactivities in locus coeruleus and noradrenergic nerve terminals in the hippocampal formation and cortex with notes on the galanin-R1 and -R2 receptors</i> , J. Comp. Neurol. 1998; 392: 227-252
CAAA	Xu Z-QD et al, <i>Galanin-5-hydroxytryptamine interactions: Electrophysiological, immunohistochemical and in situ hybridization studies on rat dorsal raphe neurons with a note on galanin R1 and R2 receptors</i> . Neuroscience 1998; 87: 79-94
CBBB	Zia S., et al., <i>Receptor-mediated inhibition of keratinocyte migration by nicotine involves modulations of calcium influx and intracellular concentration</i> , J Pharmacol Exp Ther. 2000 Jun;293(3):973-81

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